

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND )  
COMPOUNDING PHARMACY, INC. ) MDL No. 2419  
PRODUCTS LIABILITY LITIGATION ) Dkt. No. 1:13-md-2419-RWZ  
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This Document Relates to Suits Naming: )  
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Saint Thomas Outpatient Neurosurgical )  
Center, LLC )  
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**RESPONSE TO THE PSC'S STATEMENT OF UNDISPUTED MATERIAL FACTS  
IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT**  
**AND**  
**STOPNC DEFENDANTS' STATEMENT OF  
UNDISPUTED MATERIAL FACTS IN SUPPORT OF THEIR  
CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT**

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Come the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC"); Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD (frequently referred to as the "Tennessee Clinic Defendants" and herein referred to as the "STOPNC Defendants") and, pursuant to Fed. R. Civ. P. 56 and Local Rule 56.1, file this combined (1) Response to the PSC's Statement of Undisputed Material Facts in Support of Its Motion for Partial Summary Judgment and (2) Statement of Undisputed Material Facts in Support of their Cross-Motion for Partial Summary Judgment.

## **RESPONSE TO PSC'S STATEMENT OF UNDISPUTED MATERIAL FACTS**

Local Rule 56.1 requires motions for summary judgment to include a “concise statement” of undisputed material facts. The section of the PSC’s brief titled “Material Undisputed Facts” runs more than seven pages of narrative, immaterial facts, interspersed with argument and legal conclusions. The vast majority of the “facts” section is neither concise, material to the product liability issue, undisputed, nor fact.

The following subsections in the Plaintiffs’ “facts” section are not *material* to the product liability claim:

- A. Compounding Pharmacies Are Generally Not Regulated by the FDA.
- B. Risks of Pharmacy Compounding Known Before Meningitis Catastrophe.
- C. NECC Had a Known History of Regulatory Non-Compliance.
- D. For Reasons of Price, Saint Thomas Neurosurgical Becomes NECC’s Largest Customer.
- E. Saint Thomas Neurosurgical Did Nothing to Consider Safety When it Selected NECC.<sup>1</sup>

If these “facts” were actually material to the product liability claim, they would have been cited elsewhere in the PSC’s brief. They are not. Instead, the PSC includes this opening argument of “facts” as a transparent attempt to convince the Court that the STOPNC Defendants are somehow worthy of punishment. This is totally inappropriate and a waste of the parties’ and the Court’s time.

The Court should strike these subsections from the PSC’s motion as immaterial to the product liability issue.<sup>2</sup> Alternatively, the Court may deem them admitted for the

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<sup>1</sup> Doc. 2302 at 4-9.

<sup>2</sup> FED. R. CIV. P. 12(f) (“The court may strike from a pleading...any redundant, *immaterial*, impertinent, or scandalous matter.” (emphasis supplied)) Alternatively, the Court may deem the admitted or the limited purpose of the cross-motions for summary judgment, given their immateriality to the motions.

limited purpose of deciding the cross-motions because they are truly immaterial to the issue.<sup>3</sup>

The only subsections that are even arguably material to the Plaintiffs' product liability claim are the following:

F. Saint Thomas Neurosurgical Incentivized its Medical Director to Administer as Many Steroids as Possible, as Quickly as Possible.

G. Saint Thomas Neurosurgical Sells MPA to Patients.<sup>4</sup>

However, the PSC cannot resist inserting argument and legal conclusions into these two subsections. The PSC also includes repeated statements with no citation to the record as required by Rule 56(c) and Local Rule 56.1.<sup>5</sup> These statements cannot be considered "facts" in deciding the cross-motions.<sup>6</sup>

To the extent there are actually facts included in these sections (not argument or legal conclusion), with citations to admissible evidence in the record, the Court may deem them admitted for the limited purpose of deciding the cross-motions for summary judgment. The STOPNC Defendants do not contend that there are any disputed factual issues relevant to decide that the strict product liability claim cannot continue.

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<sup>3</sup> Obviously, the Defendants dispute "facts" like they "did nothing to consider safety" for their patients. However, that has nothing to do with the legal viability of the product liability claims. So, the Defendants will tackle these negligence issues later.

<sup>4</sup> Doc. 2302 at 9-10.

<sup>5</sup> E.g., Doc. 2302 at 9 ("Saint Thomas Neurosurgical conducted a high volume epidural steroid injection practice, incentivizing its medical director to administer as many steroids as possible, as quickly as possible." (no citation to record)); Doc. 2302 at 10 ("The testimony of the Defendant Debra Schamberg, Facilities Director for Saint Thomas Neurosurgical, clearly indicates that Saint Thomas Neurosurgical sells epidural steroids." (no citation to record)); Doc. 2302 at 11 ("Saint Thomas Neurosurgical's conduct after the meningitis catastrophe likewise demonstrates that Saint Thomas Neurosurgical is a 'seller.'") (no citation to record)).

<sup>6</sup> See FED. R. CIV. P. 56(c); Local Rule 56.1.

**STOPNC DEFENDANTS' STATEMENT OF UNDISPUTED MATERIAL FACTS**

There are undisputed material facts relevant to the Defendants' position:

1. STOPNC is an ambulatory surgery center licensed under Tennessee Code Title 68, Chapter 11 and accredited by the Joint Commission.<sup>7</sup>
2. John W. Culclasure, MD is an anesthesiologist licensed pursuant to Tennessee Code Title 63.<sup>8</sup>
3. The Plaintiffs underwent steroid injection procedures at STOPNC for treatment of back or neck pain.<sup>9</sup>
4. For example, Plaintiff Mae Parman was referred to STOPNC for epidural steroid injections to treat back, hip, and leg pain, believed to have been caused by lumbar stenosis.<sup>10</sup>
5. Prior to undergoing epidural steroid injection procedures at STOPNC, the Plaintiffs signed a consent form.<sup>11</sup>
6. During the Plaintiffs' procedures, an anesthesiologist administered methylprednisolone acetate ("MPA") procured by STOPNC from the New England Compounding Center ("NECC").<sup>12</sup>
7. Dr. Culclasure performed many of those procedures.<sup>13</sup>
8. STOPNC paid \$6.50 per one mL vial of MPA from NECC.<sup>14</sup>
9. Each vial contained 80 mg of MPA.<sup>15</sup>

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<sup>7</sup> Culclasure Aff. ¶ 4.

<sup>8</sup> Culclasure Aff. ¶ 2.

<sup>9</sup> 2<sup>nd</sup> Am. Master Compl. ¶¶ 151-154; Culclasure Aff. ¶¶ 7-8.

<sup>10</sup> Culclasure Aff. ¶ 8.

<sup>11</sup> Culclasure Aff. ¶ 9.

<sup>12</sup> 2<sup>nd</sup> Am. Master Compl. ¶¶ 153, 174; Culclasure Aff. ¶¶ 6, 7

<sup>13</sup> Culclasure Aff. ¶ 7.

<sup>14</sup> Culclasure Aff. ¶ 6.

<sup>15</sup> Culclasure Aff. ¶ 6.

10. Two fees were charged for the epidural steroid injections: a physician fee by Dr. Culclasure, and a facility fee by STOPNC.<sup>16</sup>

11. Dr. Culclasure charged the Plaintiffs and/or their insurers the physician fee for his professional services during the epidural steroid injection procedures.<sup>17</sup>

12. STOPNC charged the Plaintiffs and/or their insurers a facility fee of approximately \$1,034,<sup>18</sup> which was a single, global fee for the epidural steroid injections that covered all aspects of the procedure furnished by STOPNC, including:

- a. A licensed registered nurse to assess the patient's condition prior to the procedure and after the procedure, and to discharge the patient
- b. A certified medical assistant, licensed practical nurse, or a certified radiology technician to assist the physician in performing the procedure
- c. Use of STOPNC's facility, including patient rooms and an operating room
- d. Use of STOPNC's equipment, including (1) a fluoroscopy (x-ray) machine to provide the physician with a real-time imaging of the patient's spine and (2) equipment to monitor the patient's vital signs, both used during the procedure
- e. The medications administered during the procedure, including the steroid, contrast dye, saline, and local anesthetic
- f. The medical supplies used during the procedure, including latex gloves, gauze, and bandages
- g. Administrative services such as recordkeeping, billing, and scheduling.<sup>19</sup>

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<sup>16</sup> Culclasure Aff. ¶¶ 10, 11.

<sup>17</sup> Culclasure Aff. ¶ 10.

<sup>18</sup> The charge varied somewhat based on the precise type of injection performed.

<sup>19</sup> Culclasure Aff. ¶ 11.

13. A separate billing code exists for charging separately for medication administered to patients.<sup>20</sup>

14. STOPNC did not submit a separate charge to the Plaintiffs or their insurers specifically for the MPA.<sup>21</sup>

15. STOPNC did not collect sales tax from the Plaintiffs or their insurers for the MPA.<sup>22</sup>

16. Many of the Plaintiffs are Medicare beneficiaries.<sup>23</sup>

17. STOPNC billed Medicare beneficiaries and non-Medicare patients in the same manner (*i.e.*, using the same billing codes). The only difference was the reimbursement received by STOPNC, which varied to some degree based on the payor.<sup>24</sup>

18. STOPNC did not deduct the cost of the medical supplies used during the Plaintiffs' procedures as "costs of goods sold" from its income for tax purposes.<sup>25</sup>

19. Dr. Culclasure typically administered 80 mg of MPA (a single vial) to the Plaintiffs during their procedures.<sup>26</sup>

20. However, for some Plaintiffs, Dr. Culclasure administered 120 mg of MPA (one and a half vials) during their procedures.<sup>27</sup>

21. STOPNC's charge for the procedure remained the same, regardless of the number of vials of MPA used by Dr. Culclasure.<sup>28</sup>

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<sup>20</sup> See PSC's Responses to Requests for Admissions 1 and 2 and PSC's Supplemental Response to Interrogatory 1.

<sup>21</sup> Butler Aff. ¶ 10.

<sup>22</sup> Butler Aff. ¶ 12.

<sup>23</sup> Butler Aff. ¶ 8.

<sup>24</sup> Butler Aff. ¶ 9.

<sup>25</sup> Butler Aff. ¶ 13.

<sup>26</sup> Culclasure Aff. ¶ 12.

<sup>27</sup> Culclasure Aff. ¶ 12.

<sup>28</sup> Culclasure Aff. ¶ 13.

22. If Dr. Culclasure used only part of a vial of MPA, the remainder was destroyed.<sup>29</sup>

23. STOPNC performs the following procedures to treat its patients' pain: steroid injections, radiofrequency ablations (denervations), spinal cord stimulator trials, diagnostic facet joint injections, hardware blocks, and nerve root blocks.<sup>30</sup>

24. During a radiofrequency ablation, the nerves causing the patient's back or neck pain are heated using radio waves.<sup>31</sup> When the procedure is successful, the heat leaves a lesion on the nerve that prevents pain signals from reaching the brain, providing pain relief.<sup>32</sup>

25. Radiofrequency ablations do not rely on medication to provide pain relief.<sup>33</sup>

26. STOPNC is typically reimbursed approximately \$370 for epidural steroid injections by patients or their insurers.<sup>34</sup>

27. The medical supplies used during an epidural steroid injection, including the MPA, typically cost less than \$40 total.<sup>35</sup>

28. STOPNC has contracts with BlueCross BlueShield of Tennessee, Cigna HealthCare of Tennessee, and MissionPoint Health Partners.<sup>36</sup>

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<sup>29</sup> Culclasure Aff. ¶ 14.

<sup>30</sup> Culclasure Aff. ¶ 5.

<sup>31</sup> Culclasure Aff. ¶ 15.

<sup>32</sup> Culclasure Aff. ¶ 15.

<sup>33</sup> Culclasure Aff. ¶ 16.

<sup>34</sup> Butler Aff. ¶ 11.

<sup>35</sup> Butler Aff. ¶ 14.

<sup>36</sup> Butler Aff. ¶ 15.

Respectfully submitted,

**GIDEON, COOPER & ESSARY, PLC**

/s/ Chris J. Tardio  
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**C.J. Gideon, Jr.\***

**Chris J. Tardio\***

**Alan S. Bean\*\***

**Matthew H. Cline\***

315 Deaderick Street, Suite

Nashville, TN 37238

Ph: (615) 254-0400

Fax: (615) 254-0459

[chris@gideoncooper.com](mailto:chris@gideoncooper.com)

***Attorneys for the Tennessee Clinic  
Defendants***

\* Admitted pursuant to MDL Order No. 1.

\*\* Admitted *pro hac vice*.

**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 3rd day of December, 2015.

/s/ Chris J. Tardio  
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**Chris. J. Tardio**